**FEBUXOSTAT TABLETS, 40 mg and 80 mg**

| S.No. | Category | Question | Answer |
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| **Clinical Particulars** | | | |
| 1 | Use/Indication | What is the product indicated for? | Febuxostat tablets are xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in adult patients with gout who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable.<br>For the safe and effective use of allopurinol, see allopurinol prescribing information.<br><br>Limitations of Use:<br>Febuxostat tablets are not recommended for the treatment of asymptomatic hyperuricemia. |
| 2 | Dosage | What is the recommended dosage? | The recommended febuxostat dosage is 40 mg or 80 mg once daily.<br>The recommended starting dosage of febuxostat tablets are 40 mg once daily. For patients who do not achieve a serum uric acid (sUA) less than 6 mg/dL after two weeks, the recommended febuxostat tablets dosage is 80 mg once daily.<br>Limit the dosage of febuxostat tablets to 40 mg once daily in patients with severe renal impairment. |
| 3 | Administration | How to administer? | Febuxostat tablets can be taken without regard to food or antacid use. |
| 4 | Administration | Can tablet be chewed? | Take febuxostat tablets exactly as your doctor tells you to take it. |
| 5 | Administration | Use in Pediatric Population | Safety and effectiveness of febuxostat in pediatric patients have not been established. |
| 6 | Administration | Use in Geriatric Population | No dose adjustment is necessary in geriatric patients. |
| 7 | Mechanism | Mechanism of Action | Febuxostat, a xanthine oxidase inhibitor, achieves its therapeutic effect by decreasing serum uric acid. Febuxostat is not expected to inhibit other enzymes involved in purine and pyrimidine synthesis and metabolism at therapeutic concentrations. |
| 8 | Warning | Black Box Warning | • Gout patients with established cardiovascular (CV) disease treated with febuxostat had a higher rate of CV death compared to those treated with allopurinol in a CV outcomes study.<br>• Consider the risks and benefits of febuxostat when deciding to prescribe or continue patients on febuxostat. Febuxostat should only be used in patients who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to |

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| | | | allopurinol, or for whom treatment with allopurinol is not advisable. |
| 9 | Lactation | Use in Lactation | There are no data on the presence of febuxostat in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for febuxostat and any potential adverse effects on the breastfed child from febuxostat or from the underlying maternal condition. Before taking febuxostat tablets tell your doctor about all of your medical conditions, including if you are breastfeeding or plan to breastfeed. It is not known if febuxostat passes into your breast milk. You and your doctor should decide if you should take febuxostat tablets while breastfeeding. |
| 10 | Pregnancy | Use in Pregnancy | Limited available data with febuxostat use in pregnant women are insufficient to inform a drug associated risk of adverse developmental outcomes. Before taking febuxostat tablets tell your doctor about all of your medical conditions, including if you are pregnant or plan to become pregnant. It is not known if febuxostat tablets will harm your unborn baby. Talk with your doctor if you are pregnant or plan to become pregnant. |
| 11 | Precautions | Is there any interaction between medication and alcohol. | Not available |
| 12 | Storage | What are the storage conditions? | Protect from light. Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). |
| 13 | Dispensing | How to Dispense? | Dispensed in sealed bottle. Do not accept the bottle if seal over bottle is broken or missing. |
| 14 | Contraindication | What are the contraindications of (medication)? | Febuxostat is contraindicated in patients being treated with azathioprine or mercaptopurine |
| 15 | Drug Interactions | Any Drug Interactions? | Concomitant administration of Febuxostat with Xanthine Oxidase substrate drugs, azathioprine or mercaptopurine could increase plasma concentrations of these drugs resulting in severe toxicity. |
| **Pharmaceutical Particulars** | | | |
| 16 | Pharmaceutical Form | How is it supplied? | Febuxostat 40 mg tablets are green colored, round shaped, biconvex, film coated tablets, debossed with "40" on one side and "F" on other side and supplied as:<br>Bottles of 30 tablets (NDC 72205-028-30)<br>Bottles of 90 tablets (NDC 72205-028-90)<br>Bottles of 500 tablets (NDC 72205-028-05)<br>Febuxostat 80 mg tablets yellow colored, capsule shaped, biconvex, film coated tablets, debossed with "80" on one side and plain on other side and supplied as:<br>Bottles of 30 tablets (NDC 72205-029-30)<br>Bottles of 100 tablets (NDC 72205-029-91)<br>Bottles of 1000 tablets (NDC 72205-029-99) |

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| 17 | Ingredients | Active and Inactive | Active ingredient: febuxostat<br>Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, microcrystalline cellulose and magnesium stearate.<br>Febuxostat tablets are coated with polyvinyl alcohol, macrogol, titanium dioxide, talc, D&C yellow #10 aluminum lake, FD&C blue #1/brilliant blue FCF aluminum lake, FD&C blue #2/indigo carmine AL 3%-5% (40 mg), additionally iron oxide yellow (80 mg). |
| **Allergens** | | | |
| 18 | Ingredients | Does it contain Gluten? | No |
| 19 | Ingredients | Does it contain alcohol? | No |
| 20 | Ingredients | Does it contain dyes? | No |
| 21 | Ingredients | Does it contain Lactose? | Yes |
| 22 | Ingredients | Does it contain Nuts? | No |
| 23 | Ingredients | Does it contain Preservatives? | No |
| 24 | Ingredients | Does it contain Soy products? | No |
| 25 | Ingredients | Are all excipients are free from human or animal origin? | No. Febuxostat 40mg and 80mg contains Lactose produced from milk, that has been sourced from healthy cows |
| 26 | Ingredients | Other Substances | Febuxostat 40mg and 80mg were free from Latex, Corn, Rye, Sugar, Oats, Wheat, Spelt, Barley and Rennet.<br>Febuxostat 40mg and 80mg contain whey and casein. |
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| 27 | Miscellaneous | May I know the product availability? | Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products |
| 28 | Miscellaneous | May I know about return, refunds and reimbursement? | Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500 |
| 29 | Miscellaneous | Do you have any patient's assistance program? | Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company. |
| 30 | Miscellaneous | How do I report an adverse drug effect or reaction to Novadoz medication? | To report SUSPECTED ADVERSE REACTIONS, contact Novadoz Pharmaceuticals LLC at 1-855-668-2369 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. |
| 31 | Miscellaneous | Why does my pharmacy that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation? | Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products |

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| 32 | Miscellaneous | May I know where is this product manufactured? | **Manufactured by:**<br>MSN Laboratories Private Limited<br>Telangana – 509 228,<br>INDIA<br><br>**Distributed by:**<br>Novadoz Pharmaceuticals LLC<br>Piscataway, NJ 08854-3714 |